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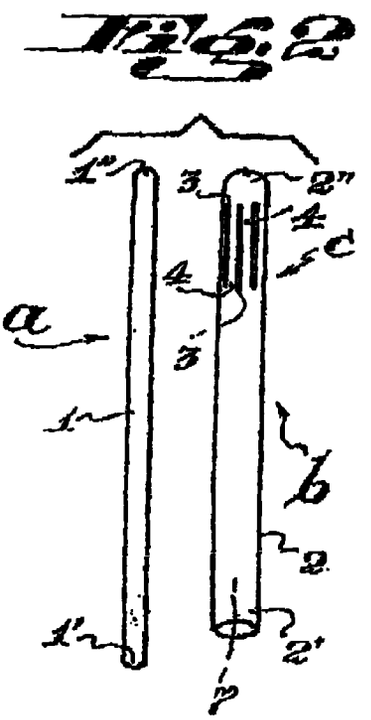
(54) Device for fixing an endovascular prosthesis in place

(57) An endovascular device for the application of prostheses (5) with sutures (9) which, making up the access route for a suture applicator (d) of the type with a rotary applicator head (8) for spiral sutures (9), can be introduced endoluminally into a vascular channel (v) for the application, the walls (b) whereof present damage to which an expandable endovascular prosthesis (5) can be applied, is **characterized** in that it comprises:

a) a support cable (a) terminating, at one end, in a distal connection end (1"), and, at the opposite end, in a proximal operative end (1');

b) a tubular part (b) that, once mounted in a sliding manner on said support cable (a), has a distal head end (2") connected with said distal connection end (1") of the above-cited support cable (1) and, at the opposite end, a proximal pushing end (2'); and

c) proximal to the distal head end (2") of said tubular part (b), and expandable segment (c) made up of a number of dilatable longitudinal cuts (3) that, forming circumstantial passages (3') for said applicator head, define a number of expander belts (4) that can be folded toward the exterior, as an expansion means for said prosthesis (5).



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Description

[0001] This invention relates to an endovascular device for application of prostheses with sutures that permit maintenance of prosthetic expansion against vascular walls while the holding sutures are applied according to the preamble of claim 1.

[0002] In pathologies affecting vascular channels, there are currently many common endovascular treatments based on the application of expandable prostheses that, like linings, allow damaged or weakened vascular walls to be supported.

[0003] Both vascular dilations subsequent to treatment and periprosthetic losses create severe problems that are difficult to solve. Recourse is had to internal sutures permitting good attachment of the prostheses for this.

[0004] These sutures consist of metal spirals provided with a sharp penetrating end and an anchoring end that are applied by means of devices dipped with rotary applicator heads. In this manner, the above-mentioned spirals pass through the walls of the prosthesis first, and then the vascular walls, achieving a very firm union by means of which the sutured prosthesis conveniently accompanies the dilation of the vascular channel.

[0005] However, the devices normally used for this type of treatment do not totally eliminate the risk of the above-mentioned periprosthetic losses or small imperfections in the union between prosthesis and vascular wall.

[0006] This is due to the fact that the prosthesis is expanded and the sutures applied in two stages. In the first stage, an inflatable balloon is generally used to expand the prosthesis against the vascular wall. Said balloon is then withdrawn and the spiral suture applicator is then introduced. It is precisely in the period between the withdrawal of the balloon and the application of the sutures that maladjustments can occur, causing serious consequences.

[0007] These problems are solved by means of this endovascular device that comprises a support cable on which a tubular pieces is mounted in a sliding manner, both connected at their respective distal ends The tubular part has a number of longitudinal cuts that, in addition to forming circumstantial passages for the suture applicator, make up an expandable segment that is simultaneously applicable to the endovascular prosthesis, keeping it expanded against the vascular walls to which it is to be applied

[0008] In this manner, the expandible segment is the tubular part not only expands the prosthesis, it also keeps it expanded while the applicator head applies the spiral sutures through the passages created by the longitudinal cuts.

[0009] Moreover, compared to some devices equipped with more complex and costly means of actuation, the simplicity of the mechanism of actuation of this device must be noted.

[0010] In effect, its operation is based on the sliding assembly of the tubular part on the support cable, as well as the distal connection between the two parts. This arrangement, by means of the simple actuation of a pushing end, allows the resistance of the folded expanding bands to be overcome such that they unfold outward until the expansion of the segment is achieved.

[0011] It is therefore a device that is simple to operate and simple in construction, which has a favorable impact on manufacturing costs.

[0012] For greater clarity and better comprehension of the subject of the invention, it is illustrated with various figures showing one of its preferred methods of embodiment, all as a simple illustrative and not limitative example:

Figure 1a is a perspective view of this device in its normally contracted position.

Figure 1b is a perspective view showing the device in its operating position, with the expandable segment in its position of maximum expansion.

Figure 2 is a cross-section showing separately the general layout of the support cable and the tubular part.

Figure 3 is a perspective view showing how the expansion of the expandable segment compresses the expandable prosthesis against the damaged vascular walls. At the same time, it shows how the longitudinal cuts form passages through which the applicator head applies the spiral sutures.

Figure 4 is a perspective view showing the general layout of this device.

[0013] In the various figures, the same reference numbers indicate the same or corresponding parts, and the sets of various components are indicated by letters.

List of the Main References:

[0014]

(a) support cable
(b) tubular part
(c) expandable segment of tubular part (b)
(d) suture applicator
(v) vascular channel for application
(1) long body of support cable(a)
(1') proximal end for operative use
(1") distal end for connection
(2) tubular walls of part (b)
2') proximal pushing end
(2") distal head end
(3) dilatable longitudinal cuts in expandable segment (c)

(3') passages shaped by longitudinal cuts (3)
(4) expander belts on expandable segment (c)
(5) expandable endovascular prosthesis
(6) injured vascular walls of vascular channel (v)
(7) tubular access passage
(8) rotary head of applicator device (d)
(9) spiral sutures applicable by means of rotary head (8)

[0015] For the purposes specified, this endovascular device for the application of prostheses (5) with sutures forming the access route for an applicator (d) of sutures (9) of the type with a rotary applicator head (8) for spiral sutures (9) can be introduced endoluminally into vascular channel (v) to which they are to be applied, the walls (6) of which present an injury to which expandable endovascular prosthesis (5) can be applied; said endovascular device is characterized in that it comprises:

a) support cable (a) terminating, at the one end, in a distal connection end (1") and, on the opposite end, in a proximal end for operative use (1');

b) a tubular part (b) that, once mounted in a slidable manner on said support cable (a), has a distal head end (2") connected with said distal connection end (1") of above-cited support cable (1) and, at the opposite end, with proximal pushing end (2'); and

c) proximal to distal head end (2") of said tubular part (b), expandable segment (c) formed of a number of dilatable longitudinal cuts (3) that, shaping circumstantial passages (3') for said applicator head (8), define a number of expander belts (4) foldable toward the exterior, as an expansion means for said prosthesis (5).

[0016] This invention consists of an **endovascular device for application of prosthesis with sutures** that, in general terms, comprises a support cable (a) on which there is mounted, in a slidable manner, tubular part (b), both (a) and (b) connected by their respective distal ends (1") (2"); said tubular part (b) has a number of longitudinal cuts (3) that, in addition to forming circumstantial passages (3') for an applicator (d) of sutures (d), also compose expandable segment (c) applicable to endovascular prosthesis (5) expandable against vascular walls (6) for the application.

[0017] In greater detail, this endovascular device is composed of support cable (a) that consists of semiflexible long body (1) that, on the one end, terminates in proximal end for operative use (1'), while the opposite end terminates in distal connection end (1").

[0018] On this support cable (a), there is mounted tubular part (b) that ends in distal head end (2"). This distal head end (2") is connected to distal connection end (1") of support cable (a) At the opposite end, tubular part (b) terminates in proximal pushing end (2').

[0019] Adjacent to above-cited distal head end (2"), tubular part (b) has expandable segment (c) in which its tubular walls (2) are affected by a number of dilatable longitudinal cuts (3). Said longitudinal cuts (3) delimit longitudinal portions of the tubular walls (2) that form expander belts (4) that can be folded toward the exterior.

[0020] In this manner, expandable segment (c) has an expansion capacity between two end positions: a normal, contracted position; and another, operating position in which expander belts (4) are folded outward and longitudinal cuts (3) dilated. In this operating position, folded expander belts (4) constitute prosthetic expansion means (5), while dilated longitudinal cuts (3) form passages (3') for an applicator head (8) for spiral sutures (9). Applicator head (8), in turns, forms part of applicator device (d) for spiral sutures (9) that accesses passages (3') of expandable segment (c) through tubular passage (7) made up of tubular walls (2).

[0021] In a preferred method of embodiment, expandable segment (c) of tubular part (b) is structured of a semi-flexible material, such that the above-cited expander belts (4) can be folded toward the exterior and retracted.

[0022] Furthermore, since support cable (a) and tubular part (b) are joined at their respective distal ends (1") (2"), proximal pushing end (2') of said tubular part (b) is mounted in a sliding manner, guided on long body (1) of above-cited cable (a), thus constituting a means of actuation for expander belts (4) that can be folded toward the exterior.

The unit functions in the following manner:

[0023] Once expandable endovascular prosthesis (5) and this device are introduced into the vascular channel for the application (v), same are positioned with regard to damaged vascular walls (6) such that the prosthesis, although not expanded, is interposed between expandable segment (c) and the above-cited vascular walls (6).

[0024] Under these conditions, if the operator operates operative end (1') of support cable (a) and, at the same time, presses, in a distal direction pushing end (2') of tubular part (b), expandable segment (c) of the latter (b) expands. This occurs because, when cable (a) and tubular part (b) are mounted in a sliding manner and connected at their respective distal ends (1")(2"), pressure exerted on pushing end (2') overcomes the resistance of expander belts (4), which fold toward the exterior.

[0025] This folding or expansion of expander belts (4) occurs against the internal walls of the prosthesis (5) which is therefore expanded against the damaged vascular walls (6), covering them.

[0026] Moreover, the expansion of the above-cited expander belts (4) causes dilation of longitudinal cuts (3) of expandable segment (c). In this manner, the

device completes its operating position in that longitudinal cuts (3) achieve their maximum dilation, forming passages (3') through which rotary head (8) of applicator device (d) for spiral sutures (9) appears. These spirals (9) first pass through the walls of prosthesis (5) and then vascular walls (6), producing the permanent attachment of prosthesis (5) in vascular channel (v).

[0027] It is indubitable that, once this device is used in practice, changes can be made in certain design and form details without escaping from the fundamental principles substantiated clearly in the following Claims.

Claims

1. ENDOVASCULAR DEVICE FOR APPLICATION OF PROSTHESES WITH SUTURES, which, making up the access route for a suture applicator of the type with a rotary applicator head for spiral sutures, can be introduced endoluminally into a vascular channel for the application, the walls whereof present damage to which an expandable endovascular prosthesis can be applied, **characterized** in that it comprises:

   a) a support cable terminating, at one end, in a distal connection end, and, at the opposite end, in a proximal operative end

   b) a tubular part that, once mounted in a sliding manner on said support cable, has a distal head end connected with said distal connection end of the above-cited support cable and, at the opposite end, a proximal pushing end; and

   c) proximal to the distal head end of said tubular part, an expandable segment made up of a number of dilatable longitudinal cuts that, forming circumstantial passages for said applicator head, define a number of expander belts that can be folded toward the exterior, as an expansion means for said prosthesis.

2. ENDOVASCULAR MEANS FOR APPLICATION OF PROSTHESIS WITH SUTURES, pursuant to Claim 1; **characterized** in that the support cable is semi-flexible.

3. ENDOVASCULAR MEANS FOR APPLICATION OF PROSTHESIS WITH SUTURES, pursuant to Claim 1; **characterized** in that the proximal pushing end of the tubular part, mounted in a guided sliding manner on the body of the support cable, composes a means of actuation of the expander belts that can be folded toward the exterior.

4. ENDOVASCULAR MEANS FOR APPLICATION OF PROSTHESIS WITH SUTURES, pursuant to Claim 1; **characterized** in that the expander belts are portions of the walls of the tubular part, delimited by longitudinal cuts that make up said walls.

5. ENDOVASCULAR MEANS FOR APPLICATION OF PROSTHESIS WITH SUTURES, pursuant to Claim 1; **characterized** in that the tubular part is composed of a semi-flexible material, while the expander belts that can be folded toward the exterior are retractable.

6. ENDOVASCULAR MEANS FOR APPLICATION OF PROSTHESIS WITH SUTURES, pursuant to Claim 1; **characterized** that the tubular part forms a tubular access passage for a suture applicator.

7. ENDOVASCULAR MEANS FOR APPLICATION OF PROSTHESIS WITH SUTURES, pursuant to Claim 1; **characterized** in that the expandable segment has an expansion capacity between two end positions: one normal contracted position; and the other operating position in which the expander belts can be folded toward the exterior -- as a means for expansion of the prosthesis -- and the dilated longitudinal cuts, which form passages for the suture applicator head.

Fig. 1a

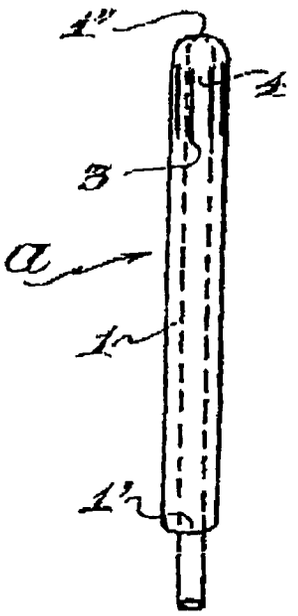


Fig. 1b

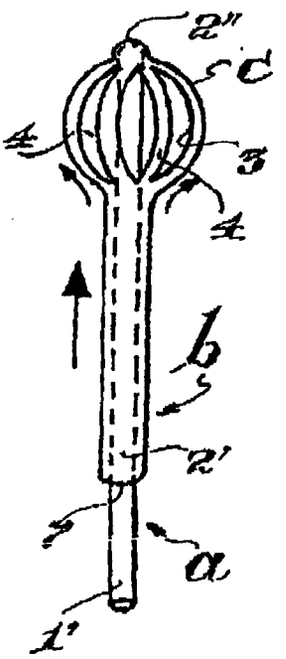
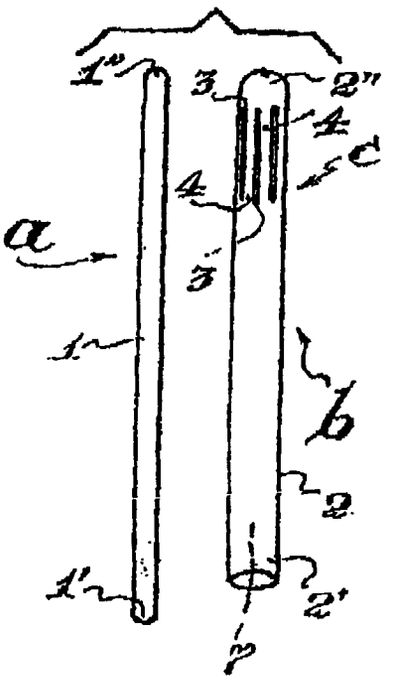


Fig. 2



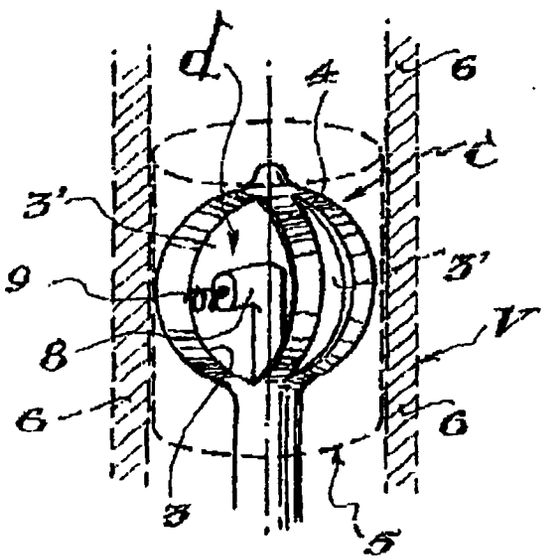


Fig. 3

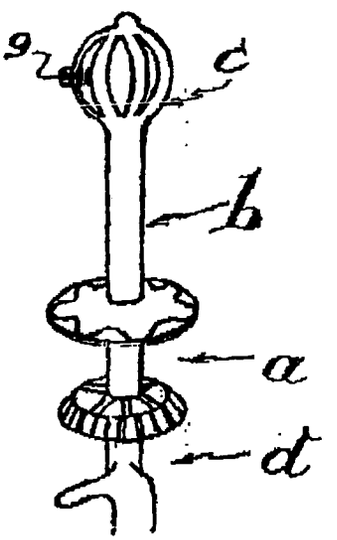


Fig. 4